DEPARTMENT OF FOOD AND AGRICULTURE

INITIAL STATEMENT OF REASONS

Hearing Date: February 3, 2009

Subject Matter of Proposed Regulations: Milk Inspection Services: Somatic Cell Counts in Milk

Section(s) Affected: Section 625

Specific Purpose of Each Adoption, Amendment, or Repeal

Existing law, section 35781 of the Food and Agricultural Code, authorizes the Department of Food and Agriculture (Department) to specify the quality standards for market milk. The Department, by regulation, may require different standards for raw market milk for pasteurization from the standards specified in law if it determines, after an administrative hearing, that the standards are necessary to protect or improve milk quality.

Existing law, section 36601 of the Food and Agricultural Code, authorizes the Department to specify, by regulation, the quality standards that are necessary for any product which is defined in Division 15 of Part 1 of said Code.

Pursuant to the above sections of law, the Department has in place section 625 of Article 21, Chapter 1, Division 2, of Title 3 of the California Code of Regulations to specify the standards for somatic cell counts in milk.

This proposal updates section 625 to specify somatic cell count standards for market milk from cows and goats, and deletes references to the California Mastitis Test (CMT). The Pasteurized Milk Ordinance (PMO), published by the United States Food and Drug Administration (FDA), no longer references the CMT as an official method for determination of somatic cells in milk.

The Department is incorporating by reference in this proposal the Standard Methods for the Examination of Dairy Products, 17th Edition (2004), published by the American Public Health Association. This proposal will bring California into conformity with federal requirements of the FDA as published in the Grade "A" PMO, 2005 Revision.

Additionally, this proposal contains organizational and formatting changes for clarity purposes.

Factual Basis

California is the leading milk producing state in the nation producing 40 billion pounds of milk, valued at approximately $7.3 billion in 2007. California currently produces over 22% of the nation's milk supply.

The Department's Milk and Dairy Food Safety Branch is charged with the mission and responsibility of ensuring that California's milk, milk products, and products resembling milk products are safe and wholesome, and meet microbiological and compositional requirements. The Department is the only state agency with comprehensive expertise, experience and training in the dairy industry from farm to table, including milk pasteurization technology and laboratory issues unique to the dairy industry.

Dairy Foods Specialists inspect dairy farms and milk processing plants, collect samples of milk and milk products to ensure consumer safety, check fail-safe systems on pasteurization equipment, and evaluate dairy farms, milk plants, and milk testing laboratories for the FDA. The Milk and Dairy Food Safety Branch also provides training and supervision for local Approved Milk Inspection Services to develop statewide uniformity in regulatory activity.

This proposal relates to milk inspection services performed by the Department or any unit of government that is approved by the Department to perform milk inspection services pursuant to sections 33141 and 33171 of the Food and Agricultural Code.

Below is the justification and rationale for this proposal.

Section 625. Somatic Cell Counts.

All milk naturally contains some somatic cells, which enable animals to fight infection and ensure good health. High somatic cell counts in milk are generally not a food safety or public health issue, but can affect dairy food manufacturing yields, product shelf life and flavor. The FDA standards, as published in the PMO, for the maximum number of somatic cells in goat milk are more stringent than the California maximum, and no longer reference the California Mastitis Test as an official test method for use in market milk. The amendments to section 625 will bring California into conformance with FDA standards.

Amend Subsection (a): This subsection incorporates by reference the official methods used to determine somatic cell counts for milk cited in the Standard Methods for the Examination of Dairy Products (SMEDP), 17th Edition (2004), published by the American Public Health Association. The SMEDP provides a system for the uniform testing of all dairy products that are a critical component of both government and industry analytical programs. The presentation of methods in SMEDP is designed to foster uniformity by providing sufficient information on key tests so that analysts have a clear set of procedures when performing each method. Due to its voluminous nature, it is not feasible to include a copy in this filing and is instead incorporated by reference.

The SMEDP methods for direct microscopic and electronic somatic cell counts are referenced in the PMO as official methods for the determination of somatic cells in market milk.

Additionally, the PMO no longer references the CMT as an official method for determination of somatic cells in milk. Therefore, the Department is deleting references to the CMT in relation to milk in this subsection to conform to FDA requirements.

Repeal Subsection (b): The Department is deleting references to the CMT and to condemnation of milk classified as a CMT 3. A CMT 3 is equivalent to over 5,000,000 somatic cells per milliliter. Current industry practices and the restricted use enforcement protocol in subsection (b) assure that milk with such levels would be unlikely. The Department also has broad authority under Food and Agricultural Code section 32761 to condemn milk or cream which is found to be impure, tainted, unclean, adulterated, or unwholesome.

Amend Subsection (c) to read Subsection (b): The Department is re-lettering this subsection to (b) and specifying the maximum count for somatic cells in market milk from cows at a maximum of 600,000 cells per milliliter, consistent with Food and Agricultural Code section 35781, and a maximum of 1,000,000 cells per milliliter in goat milk consistent with requirements in the PMO.

The term “market” milk is added in this subsection as it is terminology used in California, and is the same as “Grade A” milk, which is milk that is produced and processed under the strictest sanitary regulations. Market milk is defined in statute under Food and Agricultural Code section 32510.

The Department is also deleting references to the CMT test from this subsection in regard to restricted use procedures, as the specified counts will be used to determine compliance.

Also, this subsection deletes the word "degrade" and is replaced with "restricted use" for consistency with the wording in section 36123 of the Food and Agricultural Code.

Underlying Data

Information referenced in this proposal may be found on the Internet, or by contacting the Department, or by contacting the publishers of the documents as follows:

1) The Standard Methods for the Examination of Dairy Products, 17th Edition (2004), which is incorporated by reference in this proposal, published by the American Public Health Association, 800 I Street, NW, Washington, DC 20001-3710.

2) Information and excerpts (which are included in this filing) from the Grade "A" Pasteurized Milk Ordinance, 2005 Revision, published by the US Department of Health and Human Services, Public Health Service, Food and Drug Administration. Information regarding this publication can be found at *http://www.cfsan.fda.gov*.

Business Impact

The Department has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states.

Specific Technologies or Equipment

This regulation does mandate the use of specific technologies or equipment. However, the Department may, by regulation, adopt acceptable technologies for the dairy industry to ensure the quality standards of milk.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed regulation.